DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

D1356B

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

January 6, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Richard Bizzaro
President
Weider Nutrition International
2002 South 5070 West
Salt Lake City, Utah 84663

PURGED

Ref#-DEN-98-05

Dear Mr. Bizzaro:

This letter is written in reference to your firm's marketing and distribution of "PHENCAL" and "PHENCAL 106". Your products are offered as alternatives to the drug, Phentermine, which is a prescription drug intended to treat obesity. Labeling your products as alternatives to Phentermine represents claims that your products are intended for the same use as Phentermine. Thus, you are representing PHENCAL and PHENCAL 106 as treatments for obesity.

Additionally, brochures(labeling) titled "PHENCAL 106, The Natural Weight Loss Alternative" and "PHENCAL, Get in Control and Stop the Yo-Yo Diet" contain statements indicating that these products are also intended to treat imbalances of neurotransmitters in the brain. These statements are disease claims and not structure/function claims. Therefore these products, PHENCAL and PHENCAL 106, are drugs as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and "new drugs" [Section 201(p)] based on:

> The trade names, PHENCAL and PHENCAL 106, and statements made for both products, such as, "as effective as prescription treatment," and "...promoted weight loss at levels comparable to those shown in other clinical trials for prescription treatments."
>
> Statements in the PHENCAL brochure, such as, "If there is an imbalance of these brain chemicals [neurotransmitters] cravings and feelings of distress can occur. PHENCAL actually helps normalize these chemicals..."

Statements in the PHENCAL 106 brochure, such as, "When neurotransmitters are out of balance, cravings and feelings of distress can occur. PhenCal 106 helps balance levels of neurotransmitters, which are then utilized by the brain when needed." and "In contrast, Phen-Fen consists of Phentermine(a weak amphetamine) and Fenfluramine."

Since these drugs are "new drugs," they may not be legally marketed in the United States without approved new drug applications (Section 505(a)of the Act).

Also, PHENCAL and PHENCAL 106 are misbranded because their labeling fails to bear adequate directions for use (Section 502(f)(1)of the Act) and their labeling is false and misleading since it suggests that the products are recognized as safe and effective for their intended use (Section 502(a) of the Act) and this is not the case. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with the products.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the Food and Drug Administration, Denver District Office, Attention: Shelly L. Maifarth, Compliance Officer.

Sincerely,

PURGED

Gary C. Dean
District Director